

REMARKS

Favorable consideration and allowance of the present application is respectfully requested.

Claims 21-41, including independent claims 21, 36-37, and 39, are currently pending in the present application. Independent claim 21, for instance, is directed to a medical packaging substrate comprising a polymer-impregnated paper-based web. The web is saturated with a saturant comprising a polymer emulsion having a glass transition temperature of -20°C or less. The saturant is present at an add-on level of from about 20 to about 80 dry parts per 100 dry parts of fiber in the polymer-impregnated paper-based web. The polymer-impregnated web has a percent bacterial filtration efficiency of at least about 95%.

In the Office Action dated September 24, 2003, original independent claims 1 and 15-16 were rejected under 35 U.S.C. §102(b) or (e) as being anticipated by, or in the alternative, as being obvious under 35 U.S.C. §103(a) in view of U.S. Patent Nos. 5,576,364 to Isaac, et al.; 4,692,374 to Bouchette; or U.S. Patent No. 6,156,677 to Brown Reed, et al. Further, independent claims 1 and 15-16 were also rejected under 35 U.S.C. §102(b) as being anticipated by, or in the alternative, as being obvious under 35 U.S.C. §103(a) in view of U.S. Patent No. 5,191,734 to Weber, et al. However, Applicants respectfully submit that new independent claims 21, 36-37, and 39 patentably define over each of the above-cited references.

Brown Reed, et al. relates to a medical packaging substrate material that may be sterilized by an oxidizing gas plasma. The material may include a cellulosic

nonwoven web applied with a saturant at a level of from about 50 to about 150 wt.% based on the dry weight of the fibers. The saturant may include, for instance, poly(vinylidene chloride)-acrylonitrile-butyl acrylate copolymer, a mixture of such a polymer with a carnauba wax emulsion, or a mixture of a poly(vinylidene chloride) acrylate copolymer and a carnauba wax emulsion. (Col. 2, ll. 33-51). As correctly noted by the Examiner, Brown Reed, et al. fails to expressly disclose the claimed percent bacterial filtration efficiency (%BFE) of at least about 95%. Nevertheless, it was asserted that such a claimed %BFE value was inherent.

In response to this assertion, Applicants previously submitted the declaration of Ms. Karen H. Bean to establish that the %BFE of the product of Brown Reed, et al. was outside the claimed %BFE range.¹ With respect to the obviousness issue, Applicants also submitted the declaration of Mr. Jay R. Sommers to establish that the claimed %BFE represents a significant improvement over the %BFE found in Brown Reed, et al.² Despite such overwhelming evidence of a lack of inherency, the recent Advisory Action nonetheless indicates that "it appears that the chemistry or composition is critical in attaining a bacterial filtration efficiency." Consequently, the Advisory Action suggested amending the claims to be commensurate with the declaration.

Applicants respectfully submit, however, that independent claims 21, 36-37, and 39 do recite aspects of the saturant chemistry. For instance, each independent claim requires that the polymer emulsion have a glass transition temperature less than about

¹ Affidavit Under 37 C.F.R. § 1.132, executed by Karen H. Bean on June 30, 2003.

² Affidavit Under 37 C.F.R. § 1.132, executed by Jay R. Sommers on February 12, 2004.

-20°C. As noted in the present specification, polymer emulsions having such glass transition temperatures have been found to improve the percent bacterial filtration efficiency (%BFE) and log reduction value (LRV) of saturated paper. (Appl. p. 8, ll. 1-6). Likewise, each claim also requires that the saturant is present at a certain add-on level, e.g., from about 20 to about 80 dry parts per 100 dry parts of fiber in the polymer-impregnated paper-based web. Thus, for at least the reasons set forth above, Applicants respectfully submit that independent claims 21, 36-37, and 39 patentably define over Brown Reed, et al.

Isaac, et al. was also cited in the Office Action to reject original independent claims 1 and 15-16 under §102(b) and/or §103(a). Isaac, et al. is directed to a binder composition for use in fibrous web materials that can disintegrate into a collection of individual fibers in an aqueous medium. The binder contains (1) from about 10-40 wt.% of a water-dispersible polymer; (2) from about 10-40 wt.% of an elastomeric latex emulsion (e.g., Hystretch® V-60); (3) from about 20-40 wt.% of a xerogellant; and (4) from about 5-20 wt.% of a plasticizing agent. (Col. 6, ll. 43-49).

The web of Isaac, et al., however, is vastly different than the claimed web. For example, the web of Isaac, et al. is “importantly” designed to disintegrate or fall apart when placed in water and agitated. Consequently, Isaac, et al. states that a desirable feature is that the binder represents only a small portion by weight of the entire web. Namely, the binder components typically constitute from about 0.20-15 wt.%, particularly from about 0.20-10 wt.%, and more particularly from about 0.30-5 wt.% of the dry web. To the contrary, independent claim 21, for instance, requires that the

saturant is present at an add-on level of from about 20 to about 80 dry parts per 100 dry parts of fiber in the polymer-impregnated paper-based web. Notably, in the previous Office Action, the Examiner acknowledged that the "medical packaging substrate of the present invention is structurally distinguishable from Isaac with respect to the %BFE due to the difference in the amount of polymer emulsion present in the polymer-impregnated web." (Emphasis added).

In addition, numerous factors exist that would have prevented one of ordinary skill in the art from modifying Isaac, et al. to achieve the limitations of the present claims. For example, the low add-on level of the binder in Isaac, et al. helps facilitate the disintegration of the web in an aqueous medium. Due to this desire to maintain the web's disintegration properties, one of ordinary skill in the art would not have been motivated to increase the amount of the polymer emulsion to achieve the claimed add-on level.

Another significant factor that would have led one skilled in the art away from such a modification relates to the significant difference in the products of Isaac, et al. and the present claims. Namely, Isaac, et al. is specifically tailored for diapers, incontinent garments, and feminine care products. (Col. 1, ll. 29- 66). On the other hand, the present claims are directed to medical packaging substrates used to sterilize surgical instruments. Certainly, one seeking a saturant for sterilization applications would not have been motivated to use and make modifications to a binder designed for a diaper or other similar product. Thus, for at least the reasons set forth above,

Applicants respectfully submit that independent claims 21, 36-37, and 39 patentably define over Isaac, et al.

Apart from the references cited above, Bouchette and Weber, et al. were also cited in the previous Office Action. However, these references suffer from some of the same deficiencies discussed above. For example, Bouchette describes a material for use in an antimicrobial wet wiper, while Weber, et al. describes a material for use in agricultural mulch and row covers, bags, outer covers for personal care products (e.g., diapers, feminine pads, training pants, incontinence products, and wound dressings), surgical drapes, and gowns. Again, such products differ substantially from the medical packaging substrate of the present claims, which is specifically designed to allow for surgical instruments contained therein to become sterilized, while simultaneously acting as a good barrier to bacteria.

In any event, Bouchette and Weber, et al. also fail to disclose other limitations of the present claims. For instance, the commercially available latex binders referenced in Bouchette do not even have a glass transition temperature within the claimed range of less than about -20°C .³ Likewise, Weber, et al. completely fails to disclose the claimed %BFE value. Regardless, the recent Office Actions continue to assert that the claimed product is the same as that described in Weber, et al., and that Applicants have not demonstrated a lack of inherency. As noted above, the products are not in fact the same. In any event, Applicants emphasize that, to establish inherency, the evidence

³ Airflex A-410 and Airflex A-106 (Air Products, Inc.) are referenced at Col. 4, ll. 34-37. It is Applicants' understanding that these polymers have a glass transition temperature of $+4^{\circ}\text{C}$ and 0°C , respectively. Likewise, HA-8 (Rohm & Haas) is referenced at Col. 4, ll. 37-42. It is Applicants' understanding that this polymer has a glass transition temperature of -10°C .

must make clear that the missing descriptive matter is necessarily present in the reference, and that it would be so recognized by persons of ordinary skill in the art. The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. Thus, an inherency rejection may not be based on what would result due to the optimization of conditions, but only on what was necessarily present in the prior art. In the instant case, numerous aspects of the medical packaging substrate may be altered to influence its properties, e.g., the type of saturant polymers utilized, the add-on level, the type of web, and so forth. Thus, to obtain the claimed properties, one of ordinary skill would have to select from numerous possible conditions and parameters. Consequently, Applicants respectfully submit that the claimed properties do not necessarily flow from the teachings of the cited reference.

Applicants also respectfully submit that, at least for the reasons indicated above relating to the corresponding independent claims 21, 36-37, and 39, dependent claims 22-35, 38, and 40-41 patentably define over the references cited. However, Applicants also note that the patentability of dependent claims 22-35, 38, and 40-41 does not necessarily hinge on the patentability of the respective independent claims. In particular, some or all of these claims may possess features that are independently patentable, regardless of the patentability of the independent claims.

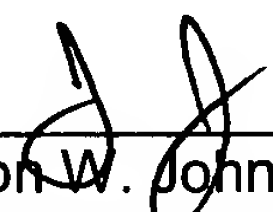
Thus, for at least the reasons set forth above, it is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner Vo is invited and encouraged to telephone the

undersigned, however, should any issues remain after consideration of this
Amendment.

Please charge any additional fees required by this Amendment to Deposit
Account No. 04-1403.

Respectfully submitted,

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